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October 20, 2020

Dear Valued Customer,

We are writing to inform of applicable codes for the Xpert® Xpress SARS-CoV-2/Flu/RSV assay. The AMA has approved two new Proprietary Laboratory Analysis (PLA) codes[1] for the Xpert® Xpress SARS-CoV-2/Flu/RSV assay.[2] The codes applicable for the Xpert® Xpress SARS-CoV-2/Flu/RSV assay are:

PLA or CPT code Applicable	Assay Target(s)	Code Descriptor
0241U	SARS-CoV-2 / Flu / RSV	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 4 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B, respiratory syncytial virus [RSV]), upper respiratory specimen, each pathogen reported as detected or not detected
0240U	SARS-CoV-2 / Flu	Infectious disease (viral respiratory tract infection), pathogen-specific RNA, 3 targets (severe acute respiratory syndrome coronavirus 2 [SARS-CoV-2], influenza A, influenza B), upper respiratory specimen, each pathogen reported as detected or not detected
87635 or **U0003*** ***U0003 is only applicable for high-throughput instruments**	SARS-CoV-2	Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique **Or** Infectious agent detection by nucleic acid (DNA or RNA); severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), amplified probe technique, making use of high throughput technologies as described by CMS-2020-01-R.

Proprietary Laboratory Analyses (PLA) Codes are an addition to the CPT® code set approved by the AMA CPT® Editorial Panel. They are alpha-numeric CPT codes with a corresponding descriptor for labs or manufacturers that want to more specifically identify their test.[3] PLA codes can be beneficial as they allow a payer to recognize certain proprietary characteristics of a particular test. PLA codes are specific to a single test informing the payer of the exact test they are providing reimbursement for, where CPT codes are generally applicable to all tests meeting the code descriptor.

[1] AMA. *CPT® Category I and Proprietary Laboratory Analyses (PLA) Codes for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) (Coronavirus Disease [COVID-19])*, 6 Oct. 2020, www.ama-assn.org/system/files/2020-10/coronavirus-long-descriptors.pdf.

[2] For use under an Emergency Use Authorization in the United States,

[3] "CPT® PLA Codes." *American Medical Association*, 2020, www.ama-assn.org/practice-management/cpt/cpt-pla-codes.

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The LOINC codes applicable for the Xpert® Xpress SARS-CoV-2/Flu/RSV assay are:

Assay Target(s)	LOINC Code[4]	LOINC Component	LOINC Property	LOINC Time	LOINC System	LOINC Scale	LOINC Method
SARS-CoV-2 / Flu / RSV	95941-1	Influenza virus A & Influenza virus B & SARS coronavirus 2 & Respiratory syncytial virus RNA panel	-	Pt	Respiratory	-	Probe.amp.tar
SARS-CoV-2 / Flu	95422-2	Influenza virus A & Influenza virus B & SARS coronavirus 2 RNA panel	-	Pt	Respiratory	-	Probe.amp.tar
SARS-CoV-2	94500-6	SARS coronavirus 2 RNA	PrThr	Pt	Respiratory	Ord	Probe.amp.tar

https://loinc.org/sars-cov-2-and-covid-19/#lab

Thank you for your continued business and your trust in Cepheid. If you have any questions, please contact Cepheid Government Affairs at GA@cepheid.com

Sincerely,

Michele Schoonmaker

Michele Schoonmaker, PhD
Vice President, Government Affairs
Cepheid

[4] "SARS-CoV-2 and COVID-19 Related LOINC Terms." *LOINC*, 21 July 2020, loinc.org/sars-cov-2-and-covid-19/.

For use under an Emergency Use Authorization in the United States. In the United States:

- This test has not been FDA cleared or approved.
- This test has been authorized by FDA under an EUA for use by authorized laboratories.
- This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acids from SARS-CoV-2, influenza A, influenza B, and respiratory syncytial virus (RSV), and not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.